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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,354	04/12/2007	Sylvie Van Der Werf	03495.0432-00000	2044

22852 7590 01/20/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,354	VAN DER WERF ET AL.	
	Examiner	Art Unit	
	BO PENG	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *5-27,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *attachment*.

DETAILED ACTION

1. The preliminary amendment filed on November 11, 2009, is acknowledged. Claims 1-31 are pending. Claims 5-20, 30 and 31 have been withdrawn. Upon further consideration, the examiner has expanded the search and examination to the subject matter of Claims 1, 3 and 4. In view of the rejoin of Claims 1, 3 and 4, the previous requirement for election of species (1)-(5), in the Restriction mailed on February 26, 2009, is withdrawn. The examiner regrets any inconvenience this may cause Applicant.

2. Accordingly, Claims 1-31 are pending. Claims 21-27, 30 and 31 have been withdrawn. Claims 1-4, 28 and 29 are examined in this Office action. Applicants are reminded to change the status of Claim 3 and 4 in response to this Office action.

Priority

3. Applicant's provision of foreign priority documents France 0314152, filing date December 2, 2003, and France 0314151, filing date December 2, 2003, is acknowledged. The English translation of the foreign priority documents has not been provided. Applicant is reminded that such priority for the claimed inventions requires support of written description and enablement under 35 U.S.C. 112, first paragraph, in the priority document. A cursory review of France 0314152 shows descriptions of plasmids encoding 14-1193, and 475-1193 of S protein SEQ ID NO: 3 on p. 14. Therefore, the priority date of Claims 1-4 is deemed to be that of France 0314151, filing date December 2, 2003.

Specification

4. (**Prior objection-withdrawn**) The objection to the specification for containing an embedded hyperlink and/or other form of browser-executable code, is withdrawn in view of the deletion of the embedded hyperlink and/or other form of browser-executable code.

Claim Objection

5. (**Prior objection-withdrawn**) The objection to Claim 2 for depending on the withdrawn Claim 1, is withdrawn for the reason set forth in Para 1.

6. (**Prior objection-maintained**) The objection to Claim 28 for containing a non-elected invention of "an antibody claimed in Claim 21" is maintained. Correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. (**Prior rejection-withdrawn**) The rejection of Claim 29 under 35 U.S.C. 102(e), as being anticipated by Vilalta *et al.* (US 20070105193, Provisional application 60/482505, filing date June 26, 2003), **is withdrawn** in favor of a new rejection set forth below.

9. (**New rejection**) Claims 1, 28 and 29 are rejected under 35 U.S.C. 102(a) as being

anticipated by Marra, *et al*. (Science 300 (5624), 1399-1404 (2003, cited in IDS), as evidenced by Genbank AY274119.3 GI:30248028 (attached to this Office action).

10. Marra *et al* teach the S protein of SARS-CoV Tor 2 strain, which has an amino acid sequence identical to the claimed S protein having the sequence of SEQ ID NO: 3. The whole sequence of the S protein of SARS-CoV Tor 2 strain are shown by Genbank AY274119.3 (see attachment to this Office action). Thus, the claimed subject matter of Claims 1, 28 and 29 is anticipated by Marra.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. (**Prior rejection-maintained-extended**) The rejection of Claims 2, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Vilalta *et al* (US 20070105193, Provisional application 60/482505, filing date June 26, 2003), **is maintained** for the reason of record.

13. Vilalta *et al* teach a polypeptide of the S protein of SARS-CoV Urbani strain, wherein the peptide of SEQ ID NO: 2 consists of amino acids 1-1196 of the S protein, see e.g. [0015] and Claims 435 and 450. The polypeptide of SEQ ID NO: 2 comprises the claimed polypeptide consisting of amino acids 1-1193 of S protein (see attached sequence alignment provided in the previous office action). Vilalta characterizes the S protein, of which amino acids 1 to about 1195

comprise an extracellular domain; amino acids from about 1196 to about 1218 are part of a transmembrane domain; and amino acids from about 1219 to about 1240 comprise the cytoplasmic domain, see Para [0031]. Vilalta explicitly suggests that removal of residues comprising the transmembrane domain and optionally, the cytoplasmic domain, results in a soluble protein that can be used in vaccine compositions [0031]. Vilalta also teaches use of the polypeptide of SEQ ID NO: 2 in a method of raising the immune response to SRAS in a vertebrate, see Abstract.

14. Vilalta does not explicitly teach a polypeptide **consisting of** amino acids 1-1193 of S protein. However, Vilalta's S polypeptide of SEQ ID NO: 2 is only three amino acids longer than the claimed polypeptide **consisting of** amino acids 1-1193 of S protein.

15. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a polypeptide consisting of amino acids 1-1193 of S peptide as an alternative or equivalent immunogenic composition as taught by Vilalta. The skilled artisan would have been motivated to do so, and would have a reasonable expectation of success, given Valalta's teachings that an S polypeptide comprising amino acids 1 to about 1195 of S protein comprises a soluble peptide, which can be used as vaccine composition. One of ordinary skill in the art would expect that the claimed S peptide would have the same function and property as the S polypeptide of SEQ ID NO: 2 of the prior art, given that the claimed S peptide has substantially the same sequence as S polypeptide of SEQ ID NO: 2 of the prior art. The three-amino acid difference in length between the prior art peptide and the claimed peptide appears to be a design choice. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

In response to the Declaration by Nicolas Escriou do under 37 C.F.R. § 1.131

16. The Declaration by Nicolas Escriou do under 37 C.F.R. § 1.131 filed on November 11, 2009, is acknowledged. In the Declaration, Nicolas Escriou do states:

"on May 12, 2003 bacteria containing the plasmids TOP10F'-SARS-S1 and TOP10F'-SARS-S2 were deposited with the Collection Nationaie de Cultures de Microorganismes (CNCM) and assigned deposit Nos. 1-3020 and 1-3019, respectively. These plasmids contain overlapping cDNAs encoding the 5' and 3' portions of the SARS-CoV and their sequences are given in the application as SEQ ID NOs: 5 and 6, respectively. *See a/so* paragraphs [0361]-[0363] and Table 1 of the published application. **Together these sequences encode the entire open reading frame of the SARS-CoV Spike protein.**" (Para 4)
"The evidence described in paragraph 4 shows that we had reduced to practice the invention claimed in the above-identified application, in France, before May 16, 2003, which is the earliest priority date claimed by Vilatta" (Para 5).

17. The Declaration by Nicolas Escriou do is considered. However, the Declaration is not sufficient to overcome the 103 rejection of Claims 2, 28, and 29 over Vilalta for the following reason. Claims 2, 28 and 29 read on an S protein fragment **consisting of** the amino acids corresponding to the amino acids 1 to 1193 of SEQ ID NO: 3. Although Applicants have reduce to practice of SARS cDNA (CNCM deposit Nos. 1-3020 and 1-3019), which encode S fragments on May 12, 2003, Applicants have not provided explicit description for the claimed S fragment **consisting of** 1-1193 until December 2, 2003, the filing date of France 0314151. Thus, the rejection is maintained.

18. (**New rejection**) Claims 1-4, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marra, *et al.* (Science 300 (5624), 1399-1404 (2003), in view of Genbank AY274119.3 GI:30248028.

19. Claims 1-4, 28 and 29 are directed to a polypeptide having the ectodomain or a fragment of the ectodomain of S protein of SEQ ID NO: 3, wherein the polypeptide consists of the amino acids 1-1193, 14-1193, and 475-1193 of S protein.

20. Note: Since the specification does not explicitly define the term of "ectodomain", the term "ectodomain" is given its general meaning as: "An ectodomain is the part of a membrane protein that extends into the extracellular space (the space outside a cell). Ectodomains are usually the part of a protein that initiates contact with surface which leads to signal transduction." (from Wikipedia, see attached).

21. The relevance of Marra is set forth *supra*.

22. However, Marra *et al*. *do not* explicitly teach an S polypeptide **consisting of** amino acids 1-1193, 14-1193, or 475-1193 of the S protein of SEQ ID NO: 3 (Claims 2-4).

23. However, Marra *et al*. provide the following teachings that would motivate or suggest to one of ordinary skill in the art to make and use S fragments containing the ectodomain (soluble domain) of S protein. Marra *et al*. teach that most of the S protein is exposed on the surface of the viral particles. The structural analysis reveals that S protein is a type I membrane protein with the *N* terminus and the majority of the protein (residues 14 to 1195) on the outside of the cell surface or virus particle. One of ordinary skill in the art would know that any viral protein exposed on the surface of viral particles is a potential antigen for a vaccine component. Marra *et al* indicate that SARS proteins and genome are useful for development of immunological tests, for the development of neutralizing antibodies, and for the identification of putative epitopes for vaccine development, see e.g. Abstract, and the Para bridging middle and right col., p. 1403.

24. The Supreme Court provided a number of bases on which a claimed invention may be

found obvious. In particular, "When there is a design need or market pressure to solve a problem and there are a finite number of identified predictable potential solutions, a person of ordinary skill has good reason to pursue the known potential options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense" (*KSR International Co. v. Teleflex Inc.* (82 U.S.P.Q. 2d1385, 2007). In the present case, the prior art has provided that there is a design need or market pressure to make antigens (immunogens) for immunological tests for detecting SARS virus, for developing neutralizing antibodies to SARS virus, and identifying epitopes for vaccine development, see e.g. Marra *et al*. Abstract, and the Para bridging middle and right col., p. 1403. The prior art has also provided a finite number of identified predictable potential solutions for making the instant S fragments of the ectodomain of S protein: (1) The prior art reference has disclosed S protein, which is identical to the instant SEQ ID NO: 3; (2) Marra *et al*. has provided structural characterization of S protein. Specifically, S protein is a type I membrane protein with the *N* terminus and the majority of the protein (residues 14 to 1195) on the outside of the cell surface or virus particle. One of ordinary skill in the art knows that the parts of viral protein exposed on the surface of viral particles are good antigens (immunogens) for vaccine component, or antigens for immunological assays (e.g. ELISA, antibody assays). Based on the prior art teachings, those of ordinary skill in the art would have made the claimed fragments of S protein containing its ectodomain using routing molecular cloning technique, and had a reasonable expectation of success in making these S fragments. In turn, because the claimed S polypeptides have the properties taught by the prior art, it would have been obvious to make the claimed S fragments. Therefore, the claimed invention is obvious over Marra *et al*., especially in the absence of

evidence to the contrary.

Remarks

25. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648